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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,439	05/08/2002	Guy Serre	217415US0PCT	4236

22850 7590 05/18/2005

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EXAMINER	
HADDAD, MAHER M	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 05/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/019,439	SERRE ET AL.	
	Examiner	Art Unit	
	Maher M. Haddad	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,5-7 and 11-22* is/are pending in the application.

4a) Of the above claim(s) *6 and 19-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,5,7,11-18 and 22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/18/05 has been entered.

2. Claims 1, 3, 5-7 and 11-22 are pending.

3. Claims 6 and 19-21 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to a nonelected invention.

4. Claims 1, 3, 5,7, 11-18 and 22 are under consideration as they read on a citrullinated polypeptide derived from all or part of the sequence of the α-chain of a vertebrate fibrin by substitution of at least one arginine residue with a citrulline residue an antigenic composition, and a kit.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1, 3, 5,7, 11-18 and 22 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a purified citrullinated polypeptide of human α-chain fibrin comprising SEQ ID NO: 1 that has a molecular weight of 64-78 KDa, by substitution of at least one arginine residue with a citrulline residue which reacts with anti-filaggrin autoantibodies, a citrullinated polypeptide resulting from the action of peptideyl arginine deiminase on the human α chain fibrin comprising SEQ ID NO: 1, or a fragment of at least 5 consecutive amino acids of a) and which also comprises at least one citrulline residue, a composition and a kit thereof for the diagnosing the presence of rheumatoid arthritis does not reasonably provide **enablement** for any purified citrullinated polypeptide which reacts with "rheumatoid arthritis-specific" anti-filagrin autoantibodies selected from a citrullinated α-chain of any "mammalian fibrin", a citrullinated polypeptide resulting from the action of peptidyle deiminase on an α-chain of "a mammalian fibrinogen" or any fragment of at least 5 consecutive amino acids of a citrullinated α-chain of a *mammalian* fibrin and which also comprises at least one citrulline residue in claim 1, any antigenic composition for diagnosing the presence of *rheumatoid arthritis-specific* anti-filaggrin autoantibodies in a biological sample, comprising at least on citrullinated polypeptide optionally labeled with or conjugated to a carrier molecule in claim 5. The specification does not enable any person skilled in the art to which it pertains, or

with which it is most nearly connected, to make and or use the invention commensurate in scope with this claim for the same reasons set forth in the previous Office Action mailed 4/21/04.

The specification discloses the citrullinated human α-chain fibrin comprising SEQ ID NO:1 with the molecular weight 64-78 was identified with anti-filaggrin autoantibodies.

Applicant's arguments, filed 1/18/05, have been fully considered, but have not been found persuasive.

Applicant has did not address the issue and therefore the rejection is maintained.

7. Claims 1, 3, 5,7, 11-18 and 22 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the same reasons set forth in the previous Office Action mailed 4/21/04.

Applicant is in possession of a a purified citrullinated polypeptide of human α-chain fibrin comprising SEQ ID NO: 1 that has a molecular weight of 64-78 KDa, by substitution of at least one arginine residue with a citrulline residue which reacts with anti-filaggrin autoantibodies, a citrullinated polypeptide resulting from the action of peptideyl arginine deiminase on the human α chain fibrin comprising SEQ ID NO: 1, or a fragment of at least 5 consecutive amino acids of a) and which also comprises at least one citrulline residue, a composition and a kit thereof for the diagnosing the presence of rheumatoid arthritis.

Applicant is not in possession of any purified citrullinated polypeptide which reacts with "rheumatoid arthritis-specific" anti-filagrin autoantibodies selected from a citrullinated α-chain of any "mammalian fibrin", a citrullinated polypeptide resulting from the action of peptidyle deiminase on an α-chain of "a mammalian fibrinogen" or any fragment of at least 5 consecutive amino acids of a citrullinated α-chain of a mammalian fibrin and which also comprises at least one citrulline residue in claim 1, any antigenic composition for diagnosing the presence of rheumatoid arthritis-specific anti-filaggrin autoantibodies in a biological sample, comprising at least on citrullinated polypeptide optionally labeled with or conjugated to a carrier molecule in claim 5.

Applicant has only disclosed purified cirtullinated human α-chain fibrin of SEQ ID NO: 1, the skilled artisan cannot envision all the contemplated mammalian fibrin sequence possibilities recited in the instant claims. Consequently, conception cannot be achieved until a representative description of the structural and functional properties of the claimed invention has occurred, regardless of the complexity or simplicity of the method. Adequate written description requires more than a mere statement that it is part of the invention.

Applicant's arguments, filed 1/18/05, have been fully considered, but have not been found persuasive.

Applicant arguments did not address the issue at hand but rather directed toward the amended claims now recite "rheumatoid arthritis-specific anti-filaggrin autoantibodies. Therefore, the rejection is maintained for the reasons of record.

8. The Declaration by Dr. Guy Serre under 37 C.F.R 1.132 filed on 1/18/05 is sufficient to overcome the rejection of claim 1(c) to the extent of human α chain fibrin fragments only based upon 35 U.S.C. § 112, first paragraph as set forth in the last Office action.

9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (571) 272-0845. The examiner can normally be reached Monday through Friday from 7:30 am to 4:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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May 6, 2005

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